510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Sheila Bruschi
Senior Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 320-4515
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MAY 14 2010

Date Prepared: May 13, 2010

B. Device Name

Trade or Proprietary Name:	*NuVasive® NeuroVision® EMG Endotracheal Tube*
Common or Usual Name:	Endotracheal Tube with Electromyography (EMG) monitoring Electrodes.
Classification Name:	Tracheal Tube Inflatable Cuff Surgical nerve stimulator/locator
Device Class:	Class II
Classification:	§874.1820, §882.1870, §868.5730 and §868.5750
Product Code:	ETN, GWF

C. Predicate Devices

The subject *NeuroVision® EMG Endotracheal Tube* is substantially equivalent to the following predicate devices currently distributed commercially in the U.S.:

- K090298 – NuVasive NeuroVision EMG Endotracheal Tube
- K032491 – ECOM™ CV4 Endotracheal Cardiac Output Monitor
- K050162 – Contact™ EMG Rotatable Endotracheal Tube

D. Device Description

The *NuVasive® NeuroVision® EMG Endotracheal (ET) Tube* is an endotracheal tube with integrated electrodes for electromyographic (EMG) monitoring during surgery. The ET tube is made of a flexible PVC material with an inflatable low pressure cuff. The *NeuroVision EMG ET Tube* is provided as a sterile, single use disposable accessory that connects to a compatible EMG monitor to provide an open airway for patient ventilation during EMG neuromonitoring of the Recurrent Laryngeal Nerve (RLN).

E. Intended Use

The *NeuroVision® EMG Endotracheal Tube* is intended for use with any compatible monitoring system during surgical procedures for continuous EMG neurological monitoring and status assessment of the nerves supplying the laryngeal musculature as well as for providing an open airway for patient ventilation.

F. Technological Characteristics

As was established in this submission, the subject *NeuroVision® EMG Endotracheal Tube* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, packaging, and sterilization. See the table below for a detailed comparison:

	Subject Device	**Predicate Devices**		
	NeuroVision EMG Endotracheal Tube	**NeuroVision EMG Endotracheal Tube (K090298)**	**ECOM CV4 Endotracheal Cardiac Output Monitor (K032491)**	**Contact™ EMG Rotatable Endotracheal Tube (K050162)**
Laryngeal Surface Electrode	YES	YES	YES	YES
Endolaryngeal Location	YES	YES	YES	YES
Number of Electrodes	4	4	*unknown*	4
Electrode Surface Material	Conductive Silver Ink	Stainless Steel Wire	Conductive Silver Ink	Stainless Steel Wire
Tube & Cuff Materials	PVC	Silicone	PVC	Silicone
Reinforcing Material	None	Stainless Steel Wire	None	Stainless Steel Wire
Tube Dimensions	Various Dimensions	Various Dimensions	*unknown*	Various Dimensions
Sterilization & Packaging	Sterile, single use only	Sterile, single use only	Sterile, single use only	Sterile, single use only

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NeuroVision® EMG Endotracheal Tube* is substantially equivalent to other predicate devices. The following testing was performed:

- Biocompatibility testing per ISO 10993-1 requirements, including:
  - cytotoxicity testing (per ISO 10993-5)
  - intracutaneous testing (per ISO 10993-10)
  - sensitization testing (per ISO 10993-10)
- Functional bench testing, including:
  - Functional testing per ISO 5361
  - inflation valve functionality
  - leak test
  - electrode resistance test
  - system integration test
  - bending test
- Stability Testing
- Sterilization & Packaging Validations

The results of these studies showed that the modified device meets the same specifications and criteria as the predecessor predicate device, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NeuroVision® EMG Endotracheal Tube* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NuVasive, Inc.
c/o Ms. Sheila Bruschi
Senior Regulatory Affairs Associate
7475 Lusk Blvd.
San Diego, CA 92121

MAY 14 2010

Re: K094054
Trade/Device Name: NuVasive® NeuroVision EMG Endotracheal Tube
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, ETN
Dated: April 12, 2010
Received: April 13, 2010

Dear Ms. Bruschi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

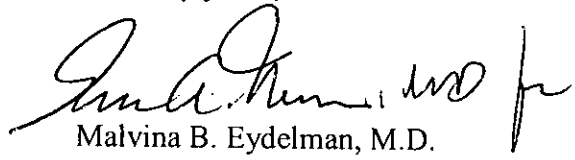
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094054

Device Name: NuVasive NeuroVision EMG Endotracheal Tube

Indications For Use:

The NeuroVision EMG Endotracheal Tube is intended for use with any compatible monitoring system during surgical procedures for continuous EMG neurological monitoring and status assessment of the nerves supplying the laryngeal musculature as well as for providing an open airway for patient ventilation.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

CG

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K094054